

Submitted written testimony of Jesse Reynolds

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My name is Jesse Reynolds, and I am Director of the Project on Biotechnology in the Public Interest at the Center for Genetics and Society. The Center is a nonpartisan information and public affairs organization working to encourage responsible uses and effective societal governance of emerging human biotechnologies. We support benign and beneficent medical applications, including human embryonic stem cell research, but recognize the need for these to be developed in a climate of appropriate oversight. The Center works in a context of support for the equitable provision of health technologies domestically and internationally; for women's health and reproductive rights; for the protection of children; for the rights of the disabled; and for precaution in the use of technologies that could alter the fundamental processes of the natural world. More information on the Center is available at our website, www.geneticsandsociety.org.

Four years ago, we were intrigued upon hearing of a proposal for California to fund stem cell research that the federal government refused to support. But when we read in detail the provisions of Proposition 71, which established the California Institute for Regenerative Medicine (CIRM), we were deeply disappointed. Because of the numerous exemptions to the norms of accountability, transparency, and oversight in the proposed constitutional amendment and statute, we felt obliged to oppose it. California had an opportunity to establish itself as a model for responsible governance of innovative medical research, but Proposition 71 forfeited that opportunity.

It was not until after the passage of the proposition that its problematic details entered the public discourse. Just a few weeks after the election, respected public figures with records of support for embryonic stem cell research, including members of the Legislature who had supported Proposition 71's passage, began to issue strong criticisms of its excesses and flaw. The Center, along with other public interest groups and experts in health law, women's health, public policy, and open government, closely followed Proposition 71's implementation. Some of our early concerns were, unfortunately, borne out.

Here, I will focus on the shortcomings in Proposition 71 itself, offering some examples of their manifestation during its implementation. My testimony will then move to specific recommendations. I believe these reforms can give us a stem cell research program of which Californians can be proud.

Fundamentals of accountability

The fundamental flaw in Proposition 71 is its creation of an agency authorized to spend significant sums of taxpayers' dollars while remaining unaccountable to the voters and their elected representatives.

Typically, the leadership of public agencies at both the national and state level is accountable through two mechanisms. Proposition 71 contains neither mechanism, resulting in a multi-billion dollar public venture that is wholly divorced from normal structures of good governance.

First, agency leaders are generally accountable, in one manner or another, to the governor or the legislature. Proposition 71 directs that members of the CIRM's 29-member governing board, the Independent Citizens' Oversight Committee (ICOC), be appointed by various elected state officials and executives of the University of California system. But neither the executive leadership of the CIRM nor the ICOC report to or are formally accountable to any elected body or official. Further, there is no mechanism for their removal.

Second, agency leadership typically must make a public case to the legislature for continued appropriations. By contrast, the CIRM is financed by a dedicated stream of special bonds, which are immune from not only any mechanism of accountability but also changing conditions. The California budget is presently in an extremely dire condition, facing a \$10 billion shortfall while numerous critical programs are slashed. Meanwhile, the original argument for Proposition 71 – that the state should fund research that the federal government would not – is fading. The incoming administration in Washington promises to greatly increase the budget of the National Institutes of Health and to remove restrictions on the federal funding of embryonic stem cell research. And in recent years, private donors have given over \$600 million to stem cell research facilities in California. Furthermore, promising new less controversial methods of stem cell research are opening the door to a wider base of public and private funding.

In addition, the initiative included unusual provisions to exempt CIRM-funded research from oversight by the state government. It states that “the institute will develop its own scientific and medical standards to carry out the specific controls and intent of the act, notwithstanding... any other current or future state laws or regulations.” Given that some legislators would like to prevent the state from funding any stem cell research, it is understandable that proponents want safeguards. But Proposition 71 goes too far.

Proposition 71 further insulated the CIRM by creating an unprecedented high bar for subsequent legislative modification. Amendments were entirely prohibited for its first three years, and now require 70% supermajorities in both houses of the Legislature, as well as the governor's signature.

This lack of accountability and oversight has been most apparent in some actions of the CIRM's leadership, particular those of the chair of the ICOC. For example, when a key Senate supporter of the CIRM convened a joint informational session of the Senate and Assembly Health Committees, he rejected the invitation, saying “The Legislature is not needed.” Since then, he has simultaneously served as the leader of both the CIRM and a series of private stem cell research lobbying organizations. If the ICOC chair were subject to appropriate structures of accountability, some of his actions as head of these lobbying groups would have come under significant scrutiny and likely have been viewed as unacceptable for a public official.

Conflicts of interest

Proposition 71's specifications for the CIRM's governing board, the ICOC, create a body characterized by inherent conflicts of interest. All board members are to represent institutions or constituencies with a vested interest in how the \$3 billion of public funds are allocated. Almost 60% of the board members are representatives of the very institutions seeking grants from the CIRM. This presents an inherent conflict of interest, as the professional success of these individuals is, in part, judged by how well they secure grants for the institutions they represent.

Most of the remainder of the ICOC is composed of disease-specific patient advocates. While they bring important voices to the board, and some individually have provided important differing perspectives, they can provide only limited balance. Proposition 71 does not include on the ICOC any perspectives independent of these interested institutions and constituencies.

One example of the kind of problems to which these built-in conflicts lead is the instance in which an ICOC member intervened on behalf of a grant application from the research institution that he also leads. This board member wrote a strongly worded seven-page letter lobbying CIRM staff to reverse a decision rejecting a grant proposal by a scientist at the research institute where he is president.

Furthermore, Proposition 71 has permitted the selection of individuals to fill its seats who have personal conflicts of interest, exacerbating the situation. Many of them have direct financial interests in the industry which is likely to benefit from public investments in stem cell research. In the spring of 2005, our research revealed that seven of the twenty-nine initial ICOC members had significant business relationships with companies involved in stem cell research. These relationships include substantial equity investments and board memberships. For example, one board member sits on the board of a California-based company dedicated to the commercialization of human stem cell products. He watered down a proposed strengthening of the ICOC's conflict of interest policies in a way that allowed him to maintain an equity stake in the company.

Exemption from state laws and other issues

Proposition 71 contains other exceptions to the norms of governance in California. The three powerful Working Groups which advise the ICOC are exempt from the Political Reform Act and the Bagley-Keane Open Meetings Act. Although their roles are technically advisory, in practice their recommendations have almost always been adopted by the ICOC. While some functions, such as personnel considerations and the critiquing of grant applications, are justified to occur behind closed doors, most of the Working Groups' functions outlined in Proposition 71 are clearly public ones.

Furthermore, although these functions include recommending which grant applications receive funding, its members need not publicly disclose relevant personal financial interests. These are provided only to the CIRM staff, who asks the grant reviewers to recuse themselves on applications in which they have an interest. This arrangement requires taxpayers to place a great degree of trust in the CIRM staff. Furthermore, it permits grant reviewers to critique applications

from the competitors of institutions or companies in which they have a financial or professional stake. When the state auditor recommended that the CIRM seek an opinion from the state attorney general on whether it should publicly disclose the reviewers' interests, the institute's leadership rejected the recommendation.

Finally, Proposition 71 was vague on the critical issue of intellectual property. This will determine if the state would receive returns on any highly-profitable discovery made with public funds, and if Californian taxpayers can afford treatments for whose developments they paid. Proposition 71's vagueness in this area is in contrast to the specific campaign promises of financial returns to the state from successful CIRM-subsidized developments.

In response to the issues raised by the Center and other public interest groups, the CIRM has adopted policies that partially mitigate some of these shortcomings. For example, meetings of the Working Groups are now public unless there are specific reasons to close the doors. Its intellectual property policy ensures some returns to the state on, and a degree of accessibility to, successful products developed with public funds, although there is room for improvement. However, these policies remain subject to modification by the ICOC.

Recommendations

I have described the flaws in Proposition 71 and have highlighted shortcomings in its implementation. I now wish to recommend changes to the statute.

Stem cell research should be publicly funded, but there is no justification for the current flawed governance structure. The most urgently needed reform to Proposition 71 is to make the CIRM appropriately accountable to the state's elected officials. This could be achieved using four mechanisms.

First, the CIRM leadership must be subject to appropriate structures of accountability. One possibility would be to make the CIRM an agency within an existing department, with the institute's governing board chaired by the director of the department. This arrangement is used by the stem cell research funding programs in New York, Connecticut, and Illinois.

Second, the elected officials who appoint the members of the ICOC should be vested with the power to replace those members.

Third, the special funds for the CIRM should no longer be allocated in a manner isolated from the budget review processes by which all other state agencies abide. Although biomedical research needs some degree of continuity, the large, untouchable set-aside for stem cell research is out of place during these difficult fiscal times.

Fourth, the exceptionally high bar for legislative modification to Proposition 71 should be lowered.

In addition to creating an accountable agency, conflicts of interest must be prevented on the ICOC. Representatives of institutions eligible for CIRM grants should serve in nonvoting,

advisory roles only. Their presence must also be balanced with a greater range of perspectives, including experts in the ethics of biotechnology, women's reproductive health, and access to biomedical technologies. Voting members of the ICOC should not be permitted to have personal financial or professional stakes in stem cell research institutions or firms.

Other aspects of Proposition 71 and the CIRM's policies, such as those governing its Working Groups, should also be examined, and some of the CIRM's existing policies regarding open meetings and intellectual property should be at least partially codified into law. But these concerns will be mitigated if the CIRM is brought under the clear authority of the state of California.

These reforms are in line with widely and generally accepted principles of accountability, transparency, and good governance. All are allowed by state law and the state constitution.

Some may charge that reform of the CIRM's governing structure to ensure greater accountability will impede urgently needed stem cell research. On the contrary: appropriate governance is essential if success is to be realized. Reasonable reforms to Proposition 71 will further the voters' mandate to support stem cell research in California.

Others may claim that the earmarked \$300 million in annual funding for CIRM grants needs to be exempted from the annual budgetary process, lest legislators and the Governor seek to use these funds for other purposes. But at the present time, funding is the last thing stem cell researchers need to worry about. The President-elect has pledged to increase federal biomedical research funding and to lift the restrictions on federal support for embryonic stem cell research. California stem cell researchers will be among the first beneficiaries of these changes. And private donors have flocked to fund stem cell research, in California and elsewhere. There is no reason to expect that ensuring greater accountability for state revenues spent on stem cell research in California will deprive this research of adequate funding.

Public oversight and responsible governance of state-funded activities are fundamental to democratic society. As the largest state-level research program in history, the CIRM should not be an exception.